Penn State Hershey CITI Course Instructions

The Penn State Hershey Human Research Protection (HRP) Educational Curriculum is available online through the Collaborative Institutional Training Initiative (CITI) courses. These instructions provide the steps for enrolling in and navigating the CITI courses. The institutional educational policy requirements are available separately, on the web at www.pennstatehershey.org/irb, under Educational Resources.

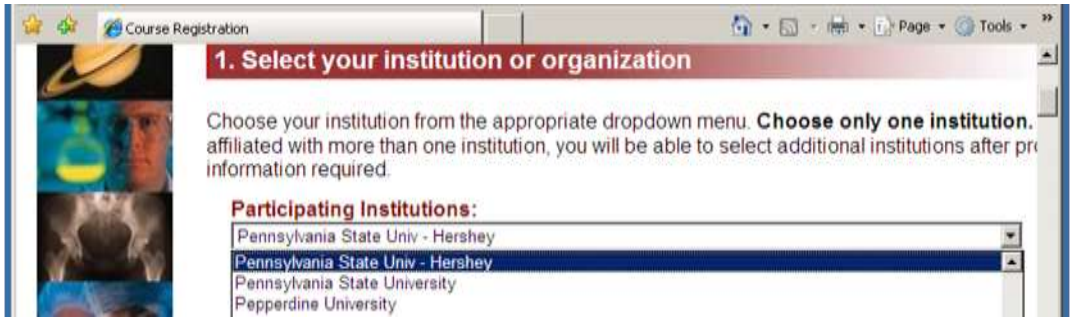
Navigation tips - For a menu illustration and tips see page 2, **CITI Navigation Tips**, which includes:
- Steps to Add a Course **-** *such as the new **Good Clinical Practice and ICH*** course;*
- Affiliate CITI Records from Another Institution - *for steps to load CITI coursework taken elsewhere; and*
- Continuing Education Requirements – *for steps to complete the 3-year course renewal requirements.*

For help - Contact the Human Subjects Protection Office, 717-531-5687, with questions about CITI access or navigation. If you have problems with re-access, the HSPO can confirm a username, and the CITI login screen provides a forgotten password feature, if needed.

***Note: Good Clinical Practice and ICH Course (GCP)** - *Additional requirement for clinical research*
Effective July 1, 2011, all key personnel on FDA-regulated research must complete the *CITI Good Clinical Practice and ICH* course (and refresher every 3 years), in addition to the *Protection of Human Research Subjects –Biomedical* course.

CITI Enrollment for New Registrants

1. Go to www.citiprogram.org and select **New Users Register Here**.
   From the list of Participating Institutions, select '**Pennsylvania State Univ - Hershey**'.
   Provide your registration details and an e-mail address to receive the renewal reminders.

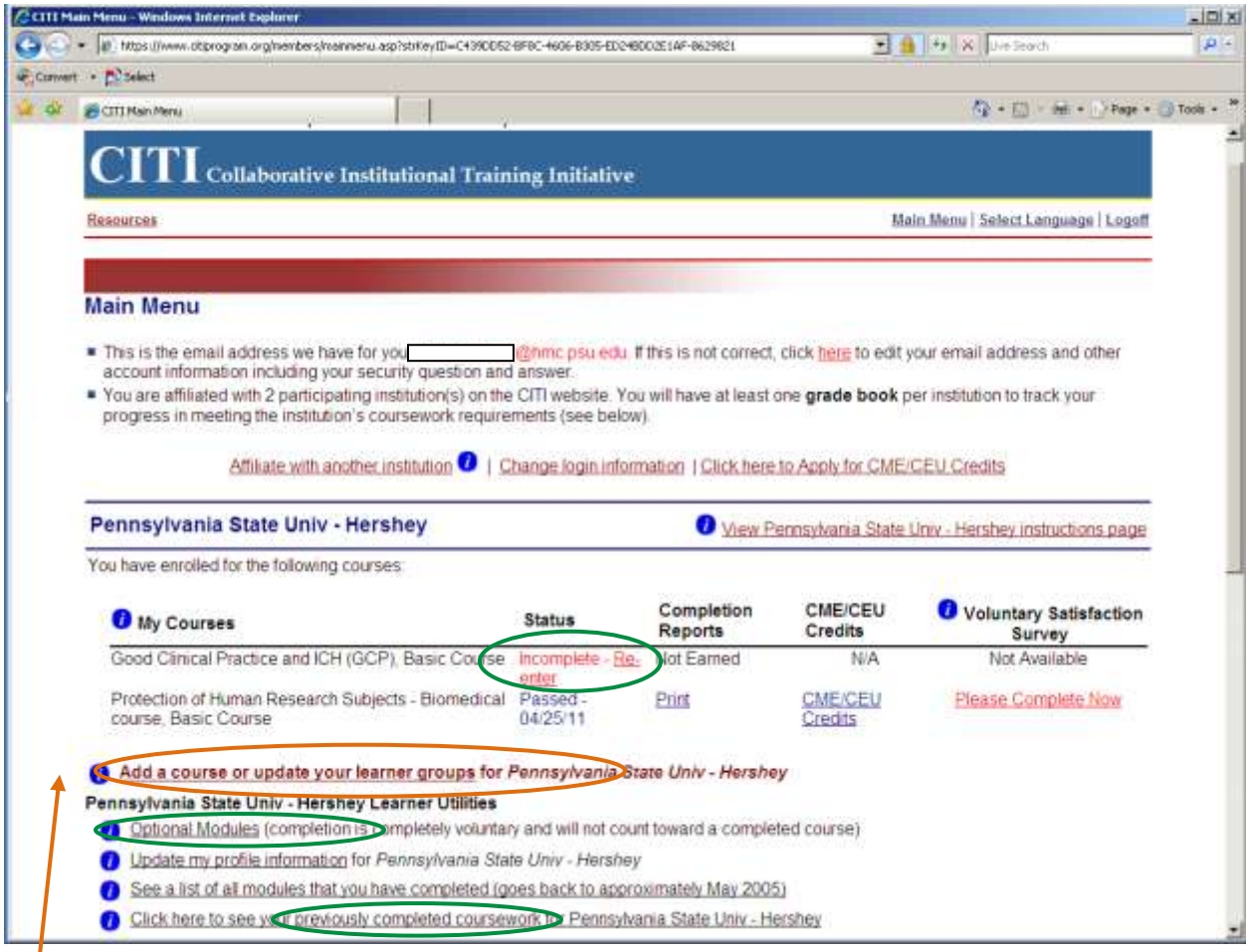


2. Under **Human Research Protection Curriculum** -
   a. **Select the core requirement -** *Protection of Human Research Subjects - Biomedical* course
   b. **Select any additional courses applicable*:**
      - Good Clinical Practice and ICH (GCP) - *required to conduct FDA-regulated research*
      - Health Information Privacy and Security (HIPS) - *optional course*

   Note: You can add additional courses later, by using **Add a Course steps on the next page*

3. Complete the coursework - *See the menu illustration and **CITI Navigation Tips** on the next page.*
   - Completion takes 3-4 hours; the modules are 15-30 minutes each. Log on and off as needed.
   - After the pre-assigned modules, if needed, select Go to Gradebook and take 1 required elective.
   - When you are finished, a certification date will post on your menu and the IRB will be notified.

CITI Navigation Tips



Status – *The main menu will list your latest enrollment selections and a link to enter incomplete courses. (If due for renewal, the next course needed will auto-load 90 days before a course expires.)*

Optional Modules - *This links to the human protection modules for reference, including all the electives.*

Previously completed coursework - *Select this link for a list of all your courses or to print completion reports.*

Add a Course or update your learner groups

At any time, log in to www.citiprogram.org, and choose the **Add a Course** link to load another course.

1. Always re-select the **Protection of Human Research Subjects – Biomedical** course first.
   - You must re-select this course so that you will receive the renewal notice when it is due.
   - If renewal is needed soon you will be asked to confirm your level; if asked, choose the Refresher.
2. Select any other course(s) you want to load, for example the **Good Clinical Practice and ICH***
   **Note: All key personnel on FDA-regulated research must complete the CITI Good Clinical Practice course requirement, in addition to the Protection of Human Research Subjects – Biomedical course.*
3. The system will return to the main menu, where any new course will be listed with a red link to enter.

Affiliate CITI Records from Another Institution

If you took CITI courses through another institution, complete the following steps to affiliate your records.

1. Complete these affiliation steps before your coursework expires, in order to avoid needing to take duplicate modules to meet a Hershey human subject educational requirement. Your current modules from the institution(s) selected will be added to your CITI Gradebook.

2. Log in at www.citiprogram.org, and select **Affiliate with another institution**.

3. Select from the list of **Participating Institutions** (based on whether you want to add a new affiliation with Hershey, or to add modules taken elsewhere to your existing Hershey CITI gradebook).
   - To newly affiliate with Hershey, choose '**Pennsylvania State Univ - Hershey**'.
   - Or choose the applicable institution to add completed modules to an existing Hershey gradebook.

4. Complete the registration fields and enrollment steps, as applicable.
   - To enroll, select the *Protection of Human Research Subjects - Biomedical* course. (See the steps in ***Add a course or update your learner groups,*** above, if needed.)
   - If you will be involved in FDA-regulated research also select *Good Clinical Practice and ICH*.

5. In order to finish the affiliation process, you must complete these last steps.
   - Once you are enrolled, go to your CITI main menu, and select the link under the 'Status' column to enter the *Protection of Human Research Subjects* course.
   - Complete any outstanding modules, which will be identified and presented 1 at a time.
   - Also, you must complete the Pennsylvania State University requirements module (listed last).
   - Finally, if you need an elective, select **Go to Gradebook** and choose one (only 1 is required).

6. Once you have met the above Penn State Univ. – Hershey curriculum requirements, a new completion date will show on your main menu (valid for 3 years) and the IRB will be notified. The CITI program will issue a renewal notice 90 days before the expiration, as explained below.

7. Remember to also complete the Good Clinical Practice and ICH module if you will be involved in FDA-regulated research. (If needed, follow the steps in *Add a course or update your learner group, above,* to add this additional course to your menu.)

Continuing Education Requirements

Penn State Hershey requires course specific continuing education renewal every 3 years for these courses:

- Protection of Human Research Subjects (Biomedical course)
- Good Clinical Practice and ICH Course (GCP)

To meet the continuing education requirement, complete the applicable *Refresher** course presented by the CITI program. You will receive a CITI e-mail renewal notice 90 days before a course expires, and the next level course for renewal will automatically load to your CITI menu at that time.

(*Note: After 1- 2 renewal cycles, depending on the course, CITI will reload the initial course again for the next renewal.)